UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

THOMAS BIONDOLILLO, Individually and on behalf of all others similarly situated, Plaintiff, v. ROCHE HOLDING AG, SEVERIN SCHWAN, ALAN HIPPE, DANIEL O'DAY and GOTTLIEB A. KELLER Defendants.	Case No. 17-cv-04056-AET-DEA **THIRD AMENDED CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

Lead Plaintiff Kevin Gardeck and named Plaintiff Thomas Biondolillo ("Plaintiffs"), by and through their attorneys, allege the following upon information and belief, except as to those allegations concerning Plaintiffs, which are alleged upon personal knowledge. Plaintiffs' information and belief is based upon, among other things, their counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Roche Holdings AG ("Roche") on the SIX Swiss Exchange ("SIX") (b) review and analysis of press releases and media reports issued by and disseminated by Roche; (c) review of other publicly available information concerning Roche; and (d) discussions with an FDA regulatory and drug development expert familiar with the relevant facts

herein. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities, other than Defendants, who purchased or otherwise acquired the publicly traded securities of Roche from March 2, 2017 through June 5, 2017, inclusive (the "Class Period"). Plaintiffs seek to recover compensable damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b), 20(a), and 20A of the Securities Exchange Act of 1934 (the "Exchange Act").

2. Roche is the largest biotechnology company in the world and a market leader in manufacturing and selling drugs used to treat cancer. Cancer drugs have netted Roche billions of dollars.

3. Roche's second highest revenue generating drug is called Herceptin. Herceptin is used to treat a type of breast cancer called HER2 positive breast cancer. Revenues from Herceptin in 2017 were an astounding $7.12 billion. However, Roche and its top management, as well as investors, knew that Herceptin would not continue to be such a massive money-maker for Roche for much longer. Herceptin's patent was set to expire, ushering in the way for competitors to supply a cheaper but nearly identical generic version of the drug to patients.

4. To offset the loss of revenues from copycat versions of Herceptin, called "biosimilars," Roche developed a strategy that consisted of both trying to increase revenues from newer drugs that would not be coming off patent anytime soon, and bundling sales of older drugs like Herceptin (whose patents were expiring) with newer drugs, selling the combination at a discount to patients who would save money buying the two drugs together (as opposed to buying the newer drug from Roche and the older drug in copycat form from a Roche competitor).

5. To that end, Roche devised the APHINITY III Study ("APHINITY," the "APHINITY study" or the "APHINITY trial)." The APHINITY study was a Phase III trial which tested whether the use of one of Roche's newer drugs, called Perjeta, in combination with the standard treatment after surgery for patients with HER2-positive breast cancer- Herceptin and chemotherapy- was more effective than just treatment with Herceptin and chemotherapy alone.

6. While Perjeta had been approved by the FDA since 2012 its use was limited as it was only used as a breast cancer drug before surgery. Revenues for Perjeta did not come close to revenues for Herceptin. But if the APHINITY study showed that adding Perjeta to the current regimen *after* surgery (known as adjuvant treatment) significantly decreased the risk of cancer returning, then not only could Roche offset revenues lost from biosimilar competition by increasing revenues

derived from Perjeta, it could continue to maintain revenues from Herceptin by selling a Perjeta/Herceptin bundle to consumers at a discount.

7. Roche and its executives were aware that because the standard after-surgery treatment of breast cancer with Herceptin and chemotherapy was so effective (it essentially cured early breast cancer in four out of five patients) doctors would need to see strong results showing significant improvement in the rate of cancer recurrence to prompt them to prescribe Perjeta in addition to the current treatment of Herceptin and chemotherapy alone. Indeed, the addition of Perjeta would increase the treatment cost for each patient by $6,100 per month. If addition of the drug did not offer substantial benefits then insurance companies would not cover its cost.

8. Roche and its executives were likewise well aware that the clinicians would weigh the benefits of adding Perjeta against the risks posed by any side effects or increases in the rates of complications and adverse events.

9. The anticipated result of the APHINITY study was the sole focus for Roche investors, as well as the Company, leading up to and during the Class Period. As one analyst stated, investors were "nearly paralyzed" pending the study read-out.

10. On March 2, 2017 Roche issued a press release (the "March 2 press release") announcing positive results from the APHINITY study, telling the market

that patients in the study who were given Perjeta lived longer without their cancer returning than patients who were not given Perjeta. The press release further stated that "no new safety signals were identified," quelling any fears that Perjeta increased the rate of adverse events.

11. In the March 2 Press Release Roche failed to disclose its financial relationship with the APHINITY Study's author and trial investigator. Indeed, over the years the APHINITY Study's author and investigator Dr. Jose Baselga received over $3 million in payments from Roche.

12. Given that payments by pharmaceutical companies to clinical researchers infects the accuracy of clinical study results, Roche was required to disclose its payments to Baselga and his involvement in the APHINITY Study in order to make Roche's statements concerning the APHINITY Study not materially misleading.

13. Analysts and investors reacted to the March 2 Press Release with vigorous enthusiasm. Analysts upgraded Roche and discussed how this excellent result removed a major overhang for Roche's stock by protecting its multibillion dollar breast cancer franchise against biosimilar competition. Indeed, shares of Roche saw the largest one day price increase in eight years.

14. The full results of the APHINITY study would not be presented for another three months, at the annual conference for the American Society of

Clinical Oncology ("ASCO"), at which point the full study results would be published. Roche insisted that presentation of the full results of the APHINITY study would have to await the June ASCO conference, but assured the market that the results were "terrific," that the data from the study was "clinically meaningful" and that the APHINITY Study demonstrated that the addition of Perjeta had broad applicability and would improve the "standard of care" "systematically."

15. Beginning one day after issuing the March 2 press release, Roche's highest executives, the Individual Defendants and members of Roche's Corporate Executive Committee, began selling shares of Roche on the Swiss Stock Exchange (the "SIX"). Over the next three months these insiders sold a total of over $13.1 million in Roche securities.

16. About three weeks after Roche executives completed their insider stock sales the ASCO conference took place and the full results of the APHINITY study were published.

17. On June 5, 2017, Roche revealed to the market the true results and data from the APHINITY study. The study results demonstrated that the addition of Perjeta after surgery showed less than a 1% benefit, barely passed the test of statistical significance, was not clinically meaningful, caused higher rates of diarrhea, and potentially increased serious cardiac toxic effects. Roche and the Individual Defendants knew this all along – particularly at the time they made their

insider sales of stock. They had all of the data from the APHINITY study as well as a statistical analysis of the study results at the time they issued the March 2 press release.

18. On this news shares of Roche fell by $1.76 per share or approximately $5.12%, damaging investors and wiping out the prior gains from the March 2 press release which misleadingly touted positive results from the APHINITY study.

19. The reaction by analysts and clinicians to the APHINITY study results was harsh. Analysts cut their forecasts and price targets on Roche. Analysts commented that the marginal efficacy, safety risks, and massive costs of adding Perjeta meant that the APHINITY study was essentially a failure and would not help insulate Roche's breast cancer franchise against biosimilar competition.

20. Oncologists- the individuals who were the ultimate decision-makers when it came time to prescribing medications- were blunt in their remarks concerning the APHINITY study results and the addition of Perjeta. One oncologist in attendance at ASCO stated "the toxic effects (and cost) are too great for too many to benefit too few." Another oncologist noted that treating 100 patients with Perjeta on top of the standard therapy would cost $10 million, stating "the study will never demonstrate a survival advantage" and concluding that "it would be irresponsible to add these to our standard regimens…" Yet another oncologist stated "[Perjeta] has not improved overall survival at all, nor has it

reduced distant relapses to a statistically significant extent… the argument for recommending adjuvant pertuzumab [Perjeta] are weak, and those for investing the huge resources demanded to pay for it are even weaker…"

21. Defendants' statements about the "terrific" study results were false and misleading and caused Roche stock to jump up and trade at artificially high prices during the Class Period. After Defendants sold their Roche stock, pocketing over $13 million, Roche disclosed the truth: that the Perjeta study results were dismal. On this news, Roche shares declined substantially causing damage to Roche investors.

22. After the close of the Class Period one of the APHINITY trial's clinical investigators, Dr. Jose Baselga, resigned from his prestigious position as Chief Medical Officer at Memorial Sloan Kettering Cancer Center after the New York Times published an expose revealing that Roche had paid Baselga over $3 million in consulting fees and for a stake of the company it acquired, a fact which Baselga (and Roche) failed to disclose.[1] ASCO stated that it would conduct an internal review of Baselga's disclosures, which violated the financial disclosure rules set by the American Association for Cancer Research. Additionally, Baselga was an Executive Member of the Breast International Group ("BIG") which Roche identified in the March 2 Press Release as one of the study collaborators "working

[1] Jose Baselga owned an equity stake in a start-up company called Seragon Pharmaceuticals. In August 2014, Roche's Genentech unit acquired Seragon.

independently from the pharmaceutical industry." While Roche noted BIG's independence, it omitted to disclose that Roche had made millions of dollars in payments to one of its Executive Members (Baselga). Baselga was one of the only Oncologists who issued positive remarks concerning the APHINITY Study at the June 5 ASCO conference.

JURISDICTION AND VENUE

23. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and §78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

24. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §1331 and §27 of the Exchange Act.

25. Venue is proper in this District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b) as the Company conducts business and a significant portion of the Defendants' actions, and the subsequent damages, took place within this District.

26. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

27. Lead Plaintiff Kevin Gardeck purchased Roche securities at artificially inflated prices during the Class Period and has been damaged thereby. His PSLRA certification was previously filed with this Court (Dkt. No. 7-2) and is incorporated by reference.

28. Plaintiff Thomas Biondolillo purchased Roche securities at artificially inflated prices during the Class Period and has been damaged thereby. His PSLRA certification was previously filed with this Court (Dkt. No. 1) and is incorporated by reference.

29. Defendant Roche is a Switzerland corporation with its principal executive offices located at Konzern Hauptsitz Grenzacherstrasse 124, CH-4070 Basel, Schweiz. Roche operates in the pharmaceuticals and diagnostics businesses worldwide. The Company's subsidiary, Roche Molecular Systems Inc., maintains offices at Building 500, 1080 U.S. Highway 202, Branchburg, NJ 08876. Roche's two primary divisions are the Pharmaceuticals Division and the Diagnostics Division. During the Class Period, the Company's ADS was actively traded on the OTCQX Marketplace under the ticker symbol "RHHBY."

30. Defendant Severin Schwan ("Schwan") has been Chief Executive Officer ("CEO") of Roche since March 2008. Schwan is also a member of Roche's 6-person Corporate Executive Committee. Schwan had personal

knowledge of the results of the APHINITY III Trial and the data from the APHINITY III Trial at the time of the March 2, 2017 press release.

31. Defendant Dr. Alan Hippe ("Hippe") has been the Chief Financial & IT Officer at Roche since April 2011. Hippe is also a member of Roche's Corporate Executive Committee. Hippe had personal knowledge of the results of the APHINITY III Trial and had the data from the APHINITY III Trial at the time of the March 2, 2017 press release.

32. Defendant Daniel O'Day ("O'Day") has been the CEO of Roche Pharmaceuticals since 2012. O'Day is also a member of Roche's Corporate Executive Committee. O'Day had personal knowledge of the results of the APHINITY III Trial and had the data from the APHINITY III Trial at the time of the March 2, 2017 press release.

33. Defendant Gottlieb A. Keller ("Keller") has been Roche's General Counsel since 2008 and worked at Roche's corporate law department since 1984. Keller is also a member of Roche's Corporate Executive Committee. Keller had personal knowledge of the results of the APHINITY III Trial and had the data from the APHINITY III Trial at the time of the March 2, 2017 press release.

34. Non-defendant Roland Diggelmann ("Diggelmann") has been the CEO of Roche Diagnostics since 2012. Digglemann is also a member of Roche's Corporate Executive Committee. Diggelmann had personal knowledge of the

results of the APHINITY III Trial and had the data from the APHINITY III Trial at the time of the March 2, 2017 press release.

35. Non-defendant Cristina A. Wilbur ("Wilbur") has been Roche's Head of Group Human Resources since March 2016. Wilbur is also a member of Roche's Corporate Executive Committee. Wilbur served as Head of Human Resources for Roche Diagnostics from 2010 to March 2016. Wilbur had personal knowledge of the results of the APHINITY III Trial and had the data from the APHINITY III Trial at the time of the March 2, 2017 press release

36. According to Roche's annual report, the Group's Corporate Executive Committee (CEC) is considered to be the Group's Chief Operating Decision Maker.

37. The members of Roche's Corporate Executive Committee during the Class Period were Defendants Schwan, Hippe, O'Day and Keller and Non-defendants Diggelmann and Wilbur.

38. Defendants Schwan, Hippe, O'Day and Keller are collectively the "Individual Defendants."

39. Each of the Individual Defendants:

(a) directly participated in the management of the Company;

(b) was directly involved in the day-to-day operations of the Company at the highest levels;

(c) was privy to confidential proprietary information concerning the Company and its business and operations;

(d) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

(e) was directly or indirectly involved in the oversight or implementation of the Company's internal controls;

(f) was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or

(g) approved or ratified these statements in violation of the federal securities laws.

40. The Company is liable for the acts of the Individual Defendants and its employees under the doctrine of *respondeat superior* and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment.

41. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to the Company under *respondeat superior* and agency principles.

42. The Company and the Individual Defendants are referred to herein, collectively, as the "Defendants."

ALLEGATIONS OF MISCONDUCT

Background

43. Roche is the world's largest biotechnology company and considers itself the global leader in cancer treatments, manufacturing numerous medicines for breast, skin, colon, ovarian, lung and numerous other cancers. Business for Roche's oncology (cancer) business accounts for more than 50% of Roche's valuation. In 2009 Genentech became a wholly owned subsidiary of Roche.

44. Sales of Roche's top three pharmaceutical products (all oncology drugs) accounted for approximately 40% of Roche's total sales prior to and during the Class Period. In 2017 Roche's top grossing product was MabThera/Rituxan, with total sales of $7.5 billion, followed closely by Herceptin, with total sales of $7.12 billion, followed by Avastin with total sales of $6.79 billion. In 2017 Roche posted total sales of $54.1 billion. Roche also invests about $10 billion in research and development each year.

45. Herceptin (trastuzumab) is a drug used to treat HER2-positive breast cancer. HER2-positive breast cancer is a particularly aggressive type of breast cancer.

46. HER2-positive breast cancer is characterized by the presence of a specific protein (receptor) called the Human Epidermal Growth Factor Receptor 2 (HER2). The HER2 protein is present on the surface of healthy cells and plays an important role in their natural life cycle. However, excessive amounts of HER2, due to a gene mutation, can lead to uncontrolled cell growth and the development of cancer.

47. Approximately one in five women diagnosed with breast cancer will have HER2-positive disease. HER2-positive disease is associated with faster disease progression and poorer chances of survival than HER2-negative disease. Globally, approximately 334,000 women are diagnosed with this type of breast cancer every year.

48. Since it was introduced in 1998, Herceptin has transformed treatment for women with HER2-positive early breast cancer, essentially curing more than four out of five patients when used with chemotherapy after surgery. Herceptin has been hailed for its efficacy in treating HER2-positive breast cancer.

49. Herceptin was Roche's first targeted cancer drug and it has dominated the HER2-positive market since its inception, with market share of over 90%.

50. Adjuvant treatment refers to treatment given to patients with early breast cancer after surgery with the aim of completely clearing any remaining cancer cells from the body and reducing the chances of the cancer returning.

51. Neoadjuvant treatment refers to treatment given to some patients with early breast cancer before surgery with the aim of shrinking the tumor, enabling an easier surgical procedure and a potentially better outcome. Neoadjuvant treatment and surgery are followed by adjuvant therapy to wipe out the remaining cancer cells in the hopes of preventing the disease from returning.

52. Three quarters of Roche's sales of Herceptin are derived from its use in adjuvant treatment, the balance is neoadjuvant or "pre-surgery".

53. Roche's Genentech unit spent decades and billions of dollars developing the blockbuster drug Herceptin. However, Herceptin's position of market domination for treatment of HER2-positive breast cancer is under threat from biosimilar competition. A biosimilar is a pharmaceutical drug designed to have active properties similar to ones that have been previously licensed. In order to lower healthcare costs through competition and increase access to lifesaving medications Congress created an abbreviated licensure pathway for biological products that are demonstrated to be biosimilar or interchangeable with an FDA-approved biological product, through the Biologics Price Competition and Innovation Act of 2009 (BCPI Act).

54. The patent on Herceptin in the EU was lost in 2014 and is due to expire in the U.S. in 2019. Patent protection of Roche's other two top drugs is likewise set to expire in the next 1-2 years. As cheaper biosimilars enter the

market more patients will switch to buying those drugs given that they are just as effective as Roche's more expensive drugs, causing Roche to lose billions of dollars in revenues.

55. Roche has tried to stop biosimilar competition of Herceptin. For example, in 2014 Roche sued a South Korean pharmaceutical firm for patent infringement in connection with the company's biosimilar of Herceptin, which had been approved in 2014. Roche lost the suit, but was successful in forestalling sales of the drug for three years, until the case was settled. In April 2017 India's antitrust regulator opened an investigation into whether Roche used its dominant position to maintain a monopoly over Herceptin after a complaint was filed by Biocon and Mylan who sell biosimilars of Herceptin in over a dozen countries alleging that Roche wrote to doctors, hospitals and regulators in an effort to mislead them about the safety and efficacy of biosimilars.

56. On December 1, 2017 the FDA approved the first biosimilar to Herceptin called Ogivri, manufactured by pharmaceutical company Mylan N.V.

57. Roche's huge impending sales decline from biosimilar competition loomed large and was widely discussed by analysts and investors leading up to and during the Class Period.

58. Roche developed a strategy to contend with biosimilar competition: conducting drug trials that not only expand the market for the drugs tested but

protect older drugs, like Herceptin, that are coming off patent. An April 27, 2017 Bloomberg article titled "Roche CEO Faces Patent Cliff With Confidence Thanks to New Drugs" stated that "Roche Holding AG is counting on new medicines- not keeping old standbys alive – as the world's biggest maker of cancer drugs faces a critical transition year." In an April 27, 2017 interview with Defendant Schwan he downplayed the threat of biosimilar competition by focusing on "innovative medicines" stating, "So yes, we will see impact from biosimilars but at the end of the day we are able to move the standard of care and replenish more mature products with our innovative medicines." Schwan made it clear in the interview though that this would require new treatments to be accepted by doctors on a broad basis, stating "[t]he answer is not that you defend your old franchises. The answer is that you move the standard of care."

59. As FiercePharma, a popular pharmaceutical industry website, stated in a February 13, 2017 article, "it's no secret that Roche's breast cancer juggernaut is about to hit a snag, and pharma watchers well know that the Swiss drugmaker has been lining up new drugs and data to steer onto a new course. The endeavor is crucial: ***The mighty Herceptin is due for U.S. biosimilar competition in the next few years, and it's a 6.8 billion Swiss franc contributor to the company's top line. Biosims in Europe are expected to erode sales beginning this year***." (Emphasis added).

60. Schwan's solution to "move the standard of care" would not be an easy task. The National Cancer Institute defines "standard of care" as "treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals. Also called best practice, standard medical care, and standard therapy." https://www.cancer.gov/publications/dictionaries/cancer-terms/def/standard-of-care. Therefore, by definition, if a new treatment is considered the "standard of care" it means that the treatment is accepted and widely used.

61. Schwan's statement that the answer is to "move the standard of care" meant that Roche intended that the Herceptin/Perjeta combination become the new, accepted and widely used treatment for HER2-positive early breast cancer in the entire applicable patient population. This would require study data strong enough to persuade oncologists to move patients from Herceptin to the combination treatment using Herceptin and Perjeta.

62. Defendants understood the risks that Roche faced given looming biosimilar competition. Defendants also knew that to offset revenues lost due to biosimilar competition, the APHINITY study would have to demonstrate broad applicability of the Herceptin/Perjeta combination in adjuvant use over the entire cross section of patients with HER2-positive early breast cancer, not just in one small subgroup of those patients.

63. The APHINITY Phase III Study ("APHINITY," the "APHINITY study" or the "APHINITY trial") was Roche's most hotly anticipated patient trial. The APHINITY III study would test a novel combination therapy, designed to protect Herceptin against the inevitable biosimilar competition. As with all Phase III trials the purpose of the APHINITY trial was to determine efficacy and monitor adverse reactions.

64. Perjeta (pertuzumab) is one of Roche's relatively newer breast cancer medications, approved by the FDA in 2012. Perjeta is approved for use with Herceptin, alongside chemotherapy, to treat metastatic and early-stage breast cancer ***before surgery***, i.e. in the ***neoadjuvant*** setting. Perjeta is not nearly as lucrative for Roche as Herceptin, generating $1.9 billion in sales in 2016. Efforts to expand the use of Perjeta also failed in a key breast cancer trial in 2014. In that trial Perjeta was combined with another Roche medication, Kadcycla, but failed to beat Herceptin and chemotherapy at progression-free survival.

65. While Perjeta (combined with Herceptin and chemotherapy) benefits patients with less advanced HER2-positive breast cancer when used ***before surgery***, expanding the market and meaningfully increasing revenues for Perjeta would require demonstrating that it was beneficial in more advanced disease, ***after surgery***, i.e. in an ***adjuvant*** setting.

66. If Roche could show that Perjeta, which would be protected by a Roche patent against competition for at least another 15 years, provided a clinically significant benefit when administered after surgery, not only would an increase in revenues from Perjeta offset revenue losses from Herceptin biosimilar competition, the sales life of Herceptin would also be extended, protecting billions in Roche revenue. Because Perjeta would only be used in combination with Herceptin, Roche would be able to offer a Herceptin-Perjeta bundle at a discount to a combination of Perjeta and a biosimilar competitor. As Bloomberg analyst Max Nisen noted: "Several of [Roche's] drug trials don't just expand the market for drugs tested. They protect older Roche medicines…Some analysts expect Perjeta, which generated close to $2 billion in sales in 2016 in its existing indications, to peak at more than $5 billion in annual sales. That's no chump change. But another sneaky benefit might be Perjeta's ability to extend the sales life of its breast-cancer-fighting-partner. Roche expects a Herceptin biosimilar to hit the U.S. market this year…Roche will likely be able to offer a Herceptin-Perjeta bundle at a discount to a combination of Perjeta and a biosimilar competitor.[2]"

67. To that end, the APHINITY study was designed to test whether the addition of Perjeta to chemotherapy and Herceptin after surgery (adjuvant treatment) improves patient outcomes.

[2] *Bloomberg*, Max Nisen, March 2, 2017.

68. The APHINITY study was conducted in 4,805 patients with HER2-positive breast cancer after receiving surgery. Half of the study patients received one year of Herceptin, chemotherapy and Perjeta. The other half of the study patients received one year of Herceptin, chemotherapy and placebo. The median follow-up[3] for patients in the study was 45 months. The clinical cutoff date for the study was December 19, 2016, meaning that all of the results and data were finalized and collected as of that date. Dr. Jose Baselga, then Chief Medical Officer of Memorial Sloan Kettering Hospital, was one of the study collaborators and is listed as a study author in the New England Journal of Medicine publication of the APHINITY study.

69. Roche sponsored the APHINITY Study, which was an international study performed in collaboration with Frontier Science Foundation and the Breast International Group ("BIG"). BIG is described in Roche's March 2 Press Release as a "not-for-profit organization for academic breast cancer research groups from around the world" which "facilitates breast cancer research at an international level, by stimulating cooperation between its members and other academic networks, and collaborating with, but working independently from, the pharmaceutical industry." At the time, Baselga was an executive member of BIG.

[3] The median follow-up refers to the time between a specified event and the time when data outcomes are gathered. The median follow-up is an indicator of how mature survival data is (e.g. how many months on average the patients were followed since randomization into the study).

70. Full results from the APHINITY study were to be received and reviewed by Roche in March of 2017. However, the full results from the trial would not be disclosed to the public until June, 2017. In June 2017 the full results from the APHINITY study would be presented publicly at the largest and most important event for clinical oncologists, pharmaceutical companies manufacturing oncology treatments (including Roche), and industry investors and analysts: the 2017 Annual ASCO Meeting[4] scheduled to take place from June 2-6, 2017 in Chicago.

Anticipation of the APHINITY Study Results

71. Leading up to and during the Class Period, the market anxiously anticipated the results from the APHINITY study. Indeed, the results from the APHINITY study were viewed by analysts and investors as being more important than even Roche's quarterly revenues and current performance. The day before the release of Roche's fourth quarter 2016 earnings, a Bloomberg analyst stated "Solid 2016 earnings may matter less than the APHINITY drug trial results, due in 1Q."

72. According to Jeffries, success for the APHINITY trial could add as much as $17 billion to Roche's market value. Failure on the other hand could erase $30 billion.

[4] ASCO is the American Society of Clinical Oncology. The Annual Meeting brings together more than 32,000 oncology professionals from around the world to discuss state-of-the-art treatment modalities, new therapies and ongoing controversies in the field. *See* https://am.asco.org/about.

73. Roche held its fourth quarter 2016 earnings call on February 1, 2017. On the call Defendant O'Day addressed the heightened anticipation surrounding the APHINITY study results: "APHINITY, we're all looking forward to those results. We expect, as I mentioned at JPMorgan, we've got all the events in now, the data is being cleaned, it's a very comprehensive study. We will have a read-out obviously between today, because I'm not announcing the APHINITY results today. And at the end of the first quarter, I can assure you as soon as we have the results, shortly after you will have the results, so I don't have any additional information on APHINITY. We have to see the read-outs as I've said before, the signals are good relative to what we've seen in neoadjuvant and elsewhere, but we'll see how the APHINITY trial reads out."

74. Indeed, results from the APHINITY study were the single thing on Roche investors' minds. A Bernstein analyst characterized investors as "nearly paralyzed" by the pending APHINITY read out.

75. Defendants were well aware that the bar for success of the APHINITY study was set high given that adjuvant treatment of HER2-positive breast cancer with the current standard of care- Herpectin plus chemotherapy- was so efficacious. Defendants knew that analysts and investors viewed a "positive" trial as one not just where the trial met its primary endpoint but one that

demonstrated a meaningful difference in reducing the risk of cancer recurrence amongst all groups of patients in the trial who were given Perjeta.

76. Defendants were aware that this meant that to be considered "positive" the addition of Perjeta would need to show at least a 20% improvement in disease free survival in the *overall* patient population. On February 15, 2017 J.P. Morgan analysts stated "we maintain our confidence in a positive trial readout ***with at least a 20% improvement in Disease Free Survival (DFS) in the overall population***." (Emphasis added).

77. UBS likewise noted the implications of any announcement by Roche that the trial results were positive. "If APHINITY is positive, Perjeta can insulate Roche from biosimilar competition against Herceptin…We find that Perjeta will need to deliver a ~20% risk reduction for the results to be statistically significant. Therefore, we think any positive result is likely to be clinically meaningful. In the US, this is probable to lead to rapid adoption."

78. Additionally, given Defendants' positions as high-ranking executives at the world's largest biotechnology company Defendants had a thorough understanding of how drug trials were conducted and were well aware of the fact that evaluations of patient benefit from a drug must weigh the magnitude of the positive effect against the potential negative side effects. Defendants were likewise aware that patients, clinicians and health insurance companies also

weighed the monetary costs of a drug against the magnitude of its benefit in deciding whether to prescribe it/provide insurance coverage for it.

79. The benefits of the combined Perjeta/Herceptin treatment tested by the APHINITY study, taking into account the costs of the treatment was widely discussed by analysts and commented on by clinicians. A February 14, 2017 Bloomberg article questioned: "will the combination continue to pay off for proposed new use? Trial results of the combination are expected by the end of March, but one of the key questions that analysts are exploring is how will it stack up against the already successful Herceptin combined with chemotherapy? And will it be cost effective compared to the older drug?"

80. The Bloomberg article went on to discuss the high bar that the study would have to reach to deem the APHINITY study a success: "…And to be considered a success, the bar is set high for Roche. The study will need to show that 90 percent of the women on the combination of Herceptin and Perjeta will see no return of their cancer for at least two years. If the combination doesn't meet that goal, up to $4.9 billion in Herceptin sales could be at risk as cheaper copies enter the market…If approved, the combination drug is expected to have a monthly price tag of about $6,000. But will that price tag be too much, especially considering that so many women are already responding so well to Herceptin treatments? That's something the data will have to show. ***If the combination drug does not***

show strong benefits, Jame Abraham, director of the Cleveland Clinic's breast oncology program, told Bloomberg the Swiss-based ***Roche will have a hard time selling the drug***." (Emphasis added).

81. Similarly, a February 15, 2015 NASDAQ article aptly titled "Roche's Herceptin and Perjeta Combination Trials Beg a Large Question" noted the weighty implications of the APHINITY study results: "Roche's results from trials of the Herceptin and Perjeta combination therapy for 'after surgery breast cancer' applications are eagerly awaited. Why? Simply because investors expect Roche to come up with novel combination therapies and make its portfolio resilient against inevitable biosimilar competition…Nearly 75% of Roche's cancer drug sales and more than 50% of its pharmaceutical sales will be impacted to an extent as competition from biosimilars emerges."

Defendants Misleadingly Tout "Positive" Results From the APHINITY Study Causing the Largest Price Increase in Roche ADS in Eight Years

82. On March 2, 2017, Roche issued a press release announcing positive results from the APHINITY study, informing the market that indeed, the addition of Perjeta to Herceptin and chemotherapy after surgery resulted in patients living longer without their cancer returning. The press release, entitled, "Phase III APHINITY study shows Roche's Perjeta® regimen helped people with an

aggressive type of early breast cancer live longer without their disease returning compared to Herceptin® and chemotherapy," stated in pertinent part:

> **Phase III APHINITY study shows Roche's Perjeta® regimen helped people with an aggressive type of early breast cancer live longer without their disease returning compared to Herceptin® and chemotherapy**
>
> - ***Perjeta plus Herceptin and chemotherapy showed a statistically significant improvement in invasive disease-free survival (iDFS) for people with HER2-positive early breast cancer (eBC) compared to Herceptin and chemotherapy alone***
> - Data will be discussed with health authorities, including the US Food and Drug Administration (FDA) and European Medicines Agency (EMA)
>
> Roche (SIX: RO, ROG; OTCQX: RHHBY), the Breast International Group (BIG), Breast European Adjuvant Study Team (BrEAST) and Frontier Science Foundation (FS) today announced positive results from the phase III APHINITY study. The study met its primary endpoint ***and showed that adjuvant (after surgery) treatment with the combination of Perjeta® (pertuzumab), Herceptin® (trastuzumab) and chemotherapy (the Perjeta-based regimen) achieved a statistically significant reduction in the risk of recurrence of invasive disease or death (invasive disease-free survival; iDFS) in people with HER2-positive early breast cancer (eBC)*** compared to Herceptin and chemotherapy alone. The safety profile of the Perjeta-based regimen was consistent with that seen in previous studies[1], and ***no new safety signals were identified***. Full results from the APHINITY trial will be presented at an upcoming medical meeting in 2017.

(Emphasis added).

83. The announcement of this long awaited good news caused the largest one-day increase in the price of Roche shares in eight years, according to

Bloomberg. On March 2, Roche ADS closed nearly 6% higher than the day prior, trading at over four times the prior day's volume.

84. Analysts and investors reacted to the press release with vigorous enthusiasm. Analysts upgraded Roche and issued positive statements. Investors traded the shares up at substantially higher than average volume. Jeffries rated Roche a "buy" noting "Wait is over, though need details to assess full upside…If Perjeta/Herceptin combination becomes the new gold standard treatment in the adjuvant treatment of HER2+ breast cancer it will also help protect the current Herceptin franchise from biosimilar threat. ***This is crucially important as around three-quarters of Herceptin's sales come from adjuvant use***." (Emphasis added).

85. Responding to the good news, Morgan Stanley rated Roche "overweight" with an industry view of "attractive," stating "Positive APHINITY results for Perjeta are key to protect the CHF10 bn breast cancer franchise. ***Upcoming submission suggests clinical meaningfulness data***…These positive results remove a major overhang for Roche (we and consensus were expecting up to 10% negative reaction in case of a failure). As a reminder this is a key driver to protect Roche's breast cancer franchise against upcoming biosimilars of Herceptin." (Emphasis added).

86. J.P. Morgan again reiterated that despite the limited detail in the March 2 press release Roche's statement meant that the addition of Perjeta

increased disease free survival by at least 20%: "This morning Roche announced positive results from the APHINTY trial testing whether the addition of Perjeta to Herceptin and chemotherapy in the adjuvant (post surgery) setting increased DFS (disease free survival—time when a patient is alive and their cancer has not returned). ***While there is limited detail in the press release other than the positive headline we know from our previous statistical analysis that the minimum benefit is 20% which is clinically relevant."*** (Emphasis added).

87. Reaction to this positive news was so strong that it caused shares of Roche's rival, Puma Biotechnology, which was set to report data for its breast cancer drug neratinib that year, to fall 12%.

88. Analysts noted that the tremendous market opportunity of the positive results from the APHINITY study was a terrific lift for Roche. Bloomberg analyst Naomi Kresge explained: "The study was vital for Roche to defend its cancer franchise as Herceptin, the company's second-best seller, faces its first competition from cheaper copies. The trial had a high hurdle to clear: since it was introduced in 1998, Herceptin has transformed treatment for women with an aggressive type of early breast cancer, essentially curing more than four out of five patients when used with chemotherapy after surgery. ***About 70% of Roche's $6.8 billion in Herceptin revenue last year came from patients who might benefit from the***

combination. Sales of Herceptin and Perjeta together could reach $9 billion by 2021, analysts estimated before the study went public." (Emphasis added).

89. Analysts and investors, like Defendants, were well aware that the APHINITY trial had to show a strong clinical benefit in order for it to be considered a success. As a Jeffries analyst explained: "Current Herceptin monotherapy treatment is already highly successful and represents a high hurdle to beat ***which makes the positive 'Aphinity' outcome all the more impressive.***" (Emphasis added). The analyst went on to note "…for the Perjeta/Herceptin combination to become widely used as a new standard of care, we will likely need to see a strong clinical benefit demonstrated by the data, ***as well as*** the statistically significant benefit."

90. Investors' and analysts' positive reactions to the March 2 press release demonstrate the unmistakable message Defendants conveyed in issuing it: that the APHINITY study was a success and that its results meant that the Perjeta/Herceptin combination would be prescribed by physicians treating patients with HER2-positive breast cancer after surgery.

91. Defendants insisted that presentation of the full results from the APHINITY study would have to await the June ASCO conference, but assured the market that the results were "terrific" and that the data from the study was "clinically meaningful."

92. Defendant O'Day discussed the results of the APHINITY study on Roche's April 27, 2017 first quarter investor conference call (the "1Q 2017 Investor Call"). O'Day stated: "And with the APHINITY trial, you see now that chart nicely filled out, essentially with ***one medicine in combination has been able to improve the standard of care systematically across metastatic, neoadjuvant and now adjuvant.*** APHINITY met its primary endpoint of reducing the risk of recurrence of invasive disease or death compared to Herceptin and chemo alone**.** ***And this is really I think terrific news for patients because we're really talking about a curative setting here with early breast cancer.*** We are really looking forward to presenting the results to you at ACSO….Based on the APHINITY results, I mean, ***we can absolutely be confident to continue to grow this franchise through the introduction of biosimilars***, which will start in Europe in the second half of this year." (Emphasis added). Accordingly, O'Day assured the market that the APHINITY study outcome was "terrific news" and that the improvement that Perjeta brought to breast cancer patients when used in an adjuvant setting would provide Roche with the market opportunity necessary to thwart erosion in the Company's sales growth from biosimilar competition.

93. On the 1Q 2017 Investor Conference Call Defendant O'Day fielded questions from analysts about the APHINITY study:

> Q: I know you don't want to say much on APHINITY ahead of ASCO, ***but hoping I can get your level of confidence from the***

> ***robustness of the results in another way because, as you know, there's lots of debate about the magnitude and the benefit and that sort of thing***. So consensus currently models peak Perjeta sales of around CHF[5] 4.5 billion. As a reference of course, Herceptin currently falls around CHF 7 billion a year. I'm hoping you can give us some indication whether you think those out-year numbers seem reachable or could they be too high or low.

94. O'Day responded, assuring investors that while the full results could not be divulged until the ACSO conference, the results were clinically meaningful and demonstrated a clinically meaningful reduction in the recurrence of disease in patients treated with the Perjeta/Herceptin combination:

> So yeah, you're right. I mean, obviously for the sake of the cooperative group, for our sake, for the sake of ASCO, we have to really wait until ASCO to get into the details. But suffice it to say that we think this is the data we filed, where we think ***the data shows a reduction in risk recurrence in invasive breast cancer and we think they're clinically meaningful.*** I think that's about as much as I'm going to open the envelope on today until you see the additional data. (Emphasis added).

O'Day additionally reassured the market that the use of Perjeta in an adjuvant setting would thwart biosimilar competition because Perjeta now showed a "significant increase in the standard of care" in "all the indications":

> ..[A]s we look forward at the HER2 franchise, we consider that—we're still going to compete on Herceptin. I mean, that doesn't go away. ***We've now got Perjeta showing significant increase in the standard of care and all the indications*** at a 2x price. It doesn't take a lot of faith to suggest and to be convinced that we can grow this

[5] "CHF" indicates Swiss Francs. 1 CHF equals approximately $1.07, presently. During the Class Period on average, 1 CHF was equal to approximately $1.03.

> franchise through the biosimilar erosion, particularly because, remember, the biosimilar erosion curve is not happening in one year, but it's happening over multiple years…it enters first in Europe and enters in the U.S. And of course, how it enters will allow us to make sure that we can have sufficient time to get the update on Perjeta around the globe. (Emphasis added).

The Individual Defendants and Corporate Executives Sell Over $13 Million in Roche Securities Over the Next Three Months

95. Beginning on March 3, 2017, just one day after Defendants issued the press release misleadingly touting positive results for the APHINITY study, executive members of Roche's board of directors began selling shares of Roche on the Swiss Exchange (the "SIX").

96. For issuers listed on the SIX (Swiss Exchange), executive management must submit transaction records for all purchases and sales of the issuer's securities to the SIX. These records are available on the OTC Markets website.

97. Trading on the SIX is regulated by Switzerland's Federal Act on Financial Market Infrastructures and Market Conduct in Securities and Derivatives Trading (FMIA). The SIX Swiss Exchange Listing Rules ("SIX Listing Rules") govern the listing of equity securities on the SIX. Article 56 of the SIX Listing Rules governs the disclosure of management transactions. (*See* SIX Listing Rules at pages 18-19 attached hereto as Exhibit 1). Article 56 states that an issuer whose securities have their primary listing on the SIX must ensure that members of the

board of directors and its executive committee report transactions in the issuer's equity securities or related financial instruments to the issuer. (*See* Exhibit 1, Article 56 par.2). This notification to the issuer, here Roche, must contain the name of the person responsible for the transaction, as well as other information such as the type of transaction and the value of the transaction. (*See* Exhibit 1, Article 56 par. 4). The issuer must then report that information to the SIX, except that the issuer is *not* required to report the name of the person responsible for the transaction. Accordingly, the records containing the Class Period insider sales available on the OTC Markets website do not contain the names of the individual executing the transaction.

98. Roche securities (non-voting equity securities and bearer shares) are traded on the SIX under the symbols RO (bearer shares) and ROG (non-voting equity securities). While the published notifications of management transactions on the SIX do not list the names of the specific individual who executed the transaction they do indicate whether the individual was a member of the Corporate Executive Committee.

99. During the Class Period there were six members of Roche's corporate Executive Committee: Defendant Schwan, Defendant O'Day, Defendant Hippe, Defendant Keller, non-Defendant Diggelmann, and non-Defendant Wilbur. Each of these individuals was aware of the complete results and data from the

APHINITY study on or before March 2, 2017 and understood its implications for Roche's sales, profits and share price.

100. While in possession of this material non-public information, these insiders sold over $13.1 million worth of Roche securities at artificially inflated prices.

101. As part of its compensation package, Roche issued Stock-Settled Stock Appreciation Rights (S-SARs) to certain directors, management and employees. The S-SARs give employees the right to receive non-voting equity securities reflecting the value of any appreciation in the market price of the non-voting equity securities between the grant date and the exercise date. The S-SARs have a seven-year duration and vest on a phased basis over 3 years. (*See* Roche's 2016 Finance Report, page 94, attached hereto as Exhibit 2). According to Exhibit 2, each year's S-SAR grant is made at a specific strike price equal to the market price on the date of grant, and has a specific expiration date for the S-SAR grant.

102. Roche's 2016 Finance Report indicates the total number of S-SAR's held by each of the Individual Defendants and members of the Corporate Executive Committee as of December 31, 2016 and the year of grant, strike price and expiration date. (*See* Roche 2016 Finance Report page 153, attached hereto as Exhibit 2). The 2016 Finance Report also indicates the number of S-SAR's issued to each of the Individual Defendants and members of the Corporate Executive

Committee in 2016. (*See Id*.) Likewise, Roche's 2017 Finance Report indicates the total number S-SAR's held by each of the Individual Defendants and members of the Corporate Executive Committee as of December 31, 2017, by year of grant, and the number of S-SARs issued to each of the Individual Defendants and members of the Corporate Executive Committee in 2017. (*See* Roche 2017 Finance Report, page 157, attached hereto as Exhibit 3).

103. The chart in Table 1 below shows the number of S-SARs held by the members of Roche's Corporate Executive Committee as of the 2016 year-end and as of the 2017 year-end as well as the amount of S-SAR's issued to each of those individuals in 2017. Accordingly, the number of S-SARs sold by each individual in 2017 can be determined by subtracting the number of S-SARs held by the individual as of the 2017 year-end from the number of S-SARs held by the individual as of the 2016 year-end and then subtracting the number of S-SARs issued to the individual in 2017.

104. As noted above, while the published notifications of management transactions on the SIX do not list the names of the specific individual who executed the transaction they do indicate whether the individual was a member of the Corporate Executive Committee. These transaction records also indicate the type of rights sold and provide under "further transaction details" whether the transaction was an "exersale" of Roche Stock-Settled Stock Appreciation Rights.

For transactions involving S-SARs the number of S-SARs is listed, as this number is different from the equivalent number of shares sold. For sales of S-SARs, the strike price and expiry date are listed, providing further information as to the identification of the seller.

105. The transaction records evidencing all of the Class Period insider sales of Roche S-SARs are attached hereto as Exhibit 4. These are the only insider sales of S-SAR's that took place during the entirety of 2017.

106. The chart in Table 1 indicates whether the insider transaction was for the sale of S-SARs and indicates the number of S-SARs sold per the transaction records in Exhibit 4. Based upon the information from the 2016 and 2017 Roche Finance reports which indicates the number of S-SARs each of the insiders sold in 2017, and the transaction records evidencing those sales, it is apparent that Defendants Schwan, Hippe, O'Day and Keller executed these S-SAR sales during the Class Period because the number of S-SARs in the transaction records in Exhibit 1 matches the number of S-SARs sold in 2017 per the information contained in Roche's Finance Reports[6].

[6] This is true for the transactions for all of the Individual Defendants except for Keller. Based upon the transaction records filed on the OTC Marketplace website Keller reported sales of only 15,000 S-SARs in 2017, whereas the information in the Roche Finance Reports shows that he sold 41,000 S-SARs in 2017. Roche must have failed to report 26,806 S-SARs that Keller sold during 2017. Because Diggelmann and Wilbur did not sell any S-SARs during 2017, the 15,000 S-SARs sale on 3/5/23017 had to be Keller's because Keller was the only member of the Corporate Executive Committee to own 15,000 S-SARs with a strike price of CHF157.50 and expiry date of March 2019. Keller therefore sold an additional 26,806 S-SARs during 2017 that

[Table 1]

Individual Defendant/Corp. Exec. Committee Member		**Total S-SARs Held as of 12/31/2016**	**Total S-SARs Held as of 12/31/2017**	**S-SARs Issued in 2017**	**S-SARs sold in 2017 Per Roche Finance Reports**
Schwan		275,439	319,443	85,476	41,472
Diggelmann		109,050	136,836	27,786	0
Hippe		110,187	115,788	34,191	28,590
Keller		118,303	108,549	32,052	41,806
O'Day		148,920	166,605	53,424	35,739
Wilbur		31,973	48,005	16,032	0
Seller	**Date of Sale**	**# of SSARs Sold Per OTC Transaction Records**	**ROG share equivalent**	**Proceeds in CHF**	
Schwan	5/10/2017	41,472	8,190	2,129,400	
Hippe	3/5/2017	28,590	5,476	1,423,760	
Keller	3/3/2017	15,000	5,983	1,555,580	
O'Day	3/5/2017	35,739	6,834	1,776,840	
Total		**120,801**	**26,483**	**6,885,580**	
In Dollars				**$7,092,147.4**	

107. In addition, the Roche 2017 Finance Report indicates the number of (bearer) shares as well as the number of non-voting equity securities held by each Individual Defendant and Member of the Corporate Executive Committee at the 2016 year and at the 2017 year end. A chart detailing this information is found at the top of page 157 of the Roche 2017 Finance Report, attached hereto as Exhibit 3. Based upon this information, Defendant Schwan, in addition to his sales of S-

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may have been sold during Class Period. However, this is not determinable without discovery because Roche violated SIX regulations by failing to timely report the transactions.

SARs, sold 2,796 Roche non-voting equity securities in 2017. The average price of Roche shares on the SIX during the Class Period was approximately 260 CFH per share, or $267.80. Accordingly, the proceeds of Schwan's sale of 2,796 non-voting equity securities during the Class Period is $748,769.

108. In addition to the four insider transactions involving sales of S-SARs during the Class Period, which reaped Defendants proceeds of approximately $7.1 million, six additional insider sales of Roche securities occurred during the Class Period. These six management transactions which the Individual Defendants were required to report to Roche and which Roche was require to publish on the SIX are available on OTC Markets website are attached hereto as Exhibit 5. Once again, while these transactions do not list the names of the specific individual who executed the transaction they do indicate whether the individual was a member of Roche's Corporate Executive Committee. Each of the transactions in Exhibit 5 indicates that the sale was executed by a member of the Corporate Executive Committee. In addition, these are the only sales of Roche securities (that are not S-SARs) that took place during the entirety of 2017 based upon the transaction records available on the OTC Markets website that Roche was required to publish.

109. The chart in Table 2 below shows all of the insider sales of Roche securities by members of the Corporate Executive Committee during the Class

Period and the type of rights that were sold (i.e. S-SARs, bearer shares or other securities).

[Table 2]

Date	Price in Swiss Francs	Shares	Type of Rights	Number of S-SARs	Seller if known
3/3/2017	1,567,546	5,983	S-SAR	15,000	Keller
3/29/2017	684,288	2,673	Other Securities		
3/30/2017	1,164,612	4,514	Other Securities		
5/3/2017	2,385	9	Bearer Shares		

5/3/2017	1,448,679.40	5,476	S-SAR	28,590	Hippe
5/3/2017	1,808,310.80	6,834	S-SAR	35,739	O'Day
5/2/2017	328,174.75	1,249	Bearer Shares		
5/2/2017	2,849,012	10,876	Other Securities		
5/10/2017	730,057.50	2,742	Bearer Shares		
5/10/2017	2,186,691.30	8,190	S-SAR	41,472	Schwan
Total CHF	12,769,757	48,546		120,801	
Total Dollars	$ 13,152,849				

110. As indicated by the chart in Table 2 above, members of Roche's Corporate Executive Committee sold a total of approximately $13.1 million in Roche securities during the Class Period. Of those securities, $7,092,147.4 in proceeds are attributable to sales of S-SARs held by the Individual Defendants (See Table 1 above) and approximately $748,769 in proceeds are attributable to additional non-voting equity securities that Defendant Schwan sold. The remaining $5,311,933 in proceeds are attributable to sales of securities held by members of the Corporate Executive Committee. However the limited information provided in Roche's Finance Reports and the information in the records of management transactions in Exhibits 4 and 5 do not indicate which specific individuals executed the remaining $5,311,933 in sales.

111. These ten suspiciously timed insider stock sales- which began just one day after issuance of the false and misleading March 2 press release and ceased about three weeks before the true study results were revealed at the ASCO conference- were not linked to the expiration of shares under a 10b5-1 trading plan. These sales were also suspiciously disproportionate in both the number of insider sales executed during this period as well as the proceeds received. In the same period a year earlier, there was only one insider sale valued at around 2 million Swiss francs.[7]

112. These insider sales were unusual in both timing and amount. In contrast to the ten insider sales by members of Roche's Corporate Executive Committee during the Class Period totaling $13.1 million there were only 3 insider sales by members of Roche's Corporate Executive Committee in 2016 totaling under $5.7 million (less than half the value of the insider sales during the three month Class Period), and 3 insider sales by members of Roche's Corporate Executive Committee in 2015 totaling under $2.9 million (less than one quarter of the value of the insider sales during the three month Class Period).

113. By engaging in these insider sales Defendants illegally profited in these trades between March 2, 2017, the date of the misleading announcement of

[7] Source: Wall Street Journal, August 14, 2017.

the APHINITY study's top-line results, and June 5, 2017, the date Roche announced the results of the full study presented at ASCO.

ROCHE Presents the Full Details of the APHINITY Study at ASCO Shocking Clinicians and the Market

114. On June 5, 2017, Roche revealed to the market the true results and data from the APHINITY study which demonstrated that addition of Perjeta after surgery showed less than a 1% benefit, barely passed the test of statistical significance, was not clinically meaningful, caused higher rates of diarrhea, and had serious implications for potential cardiac side effects.

115. Roche's June 5, 2017 press release revealed the following results from the APHINITY study:

> At three years, ***94.1%*** of people treated with the Perjeta-based regimen did not have their breast cancer return ***compared to 93.2%*** treated with Herceptin and chemotherapy.
>
> ***
>
> At the time of the primary analysis, with median follow-up of 45.4 months, the reduction in risk of invasive breast cancer recurrence with the Perjeta-based regimen was greatest in people with lymph node-positive (HR=0.77; 95% CI 0.62-0.96, p=0.019) or hormone receptor-negative disease (HR=0.76; 95% CI 0.56-1.04, p=0.085).[1] At three years, among people with node-positive disease, 92.0% of people treated with the Perjeta-based regimen did not have their breast cancer return compared to 90.2% treated with Herceptin and chemotherapy, and iDFS rates in the hormone receptor-negative disease subgroup were 92.8% in the Perjeta-based arm and 91.2% in the Herceptin and chemotherapy arm.[1] ***The number of events in both treatment arms***

was low in people with node-negative disease, where no benefit with the Perjeta-based regimen was detected at this time.

(Emphasis added).

116. Accordingly, the results from the APHINITY study show that among the entire patient population the rate of cancer recurrence in patients treated with Perjeta after 3 years was just 0.9% less than the rate of cancer recurrence in patients not given Perjeta after three years. This meant that Perjeta provided no meaningful clinical benefit to breast cancer patients after surgery.

117. Analyst Adam Feuerstein noted that the "p value" demonstrated by the trial was 0.045, within a "hair" of failing the test for statistical significance.

118. Worse yet, this entire purported improvement in the rate of cancer recurrence was attributable to one subgroup within the trial, patients with lymph node positive status. Accordingly, Roche's claim that the addition of Perjeta showed statistically significant improvement in disease-free survival was misleading as it was driven entirely by one subset of patients in the trial.

119. Additionally, while Roche claimed that "no new safety signals were identified" in the group of patients treated with Perjeta, the addition of Perjeta was associated with a higher rate of diarrhea: 71.2% of patients in the Perjeta group experienced grade 1 or 2 diarrhea whereas only 45.2% of patients in the placebo group did. Diarrhea in cancer patients can often lead to hospitalization and complications. Worse yet, primary cardiac events occurred in 17 patients in the

Perjeta group compared to 8 patients in the placebo group. 15 patients in the Perjeta group experienced Class III or IV heart failure and substantial decrease in left ventricular ejection fraction, compared with 6 in the placebo group. Further, the rate of patient discontinuation due to adverse events was 1.1 percentage points higher in the group of patients treated with Perjeta compared to those treated with placebo.

120. On this news, Roche ADS fell by $1.76 per share or approximately 5.12% from its previous closing price to close at $32.61 per share on June 5, 2017, damaging investors. The volume of trading in Roche ADS on June 5, 2017 was nearly ***seven and a half times*** the volume of the prior trading session. This stock price decline wiped out the prior gains from Defendants' March 2 press release which misleadingly touted positive results from the APHINITY study.

121. In the wake of this news, media outlets commented on the disappointing results. A June 5 article in the *Financial Times* stated "Roche's hopes of protecting its $7bn breast cancer franchise with a new drug cocktail were dealt a blow after a large trial showed the combination was only marginally better than an older medicine made by the company."

122. The article went on to note the marginal 0.9 percentage point difference: "After three years, 94.1 per cent of patients taking the cocktail were disease-free, versus 93.2 per cent of those on Herceptin alone, according to the

data, which were presented at the world's largest cancer meeting on Monday." The President of ASCO, Dr. Daniel Hayes was quoted in the article, commenting on the severe adverse side effects as well as the costs of the combination of the two drugs: "Dr. Hayes said oncologists might refrain from using the new combination not just for cost reasons, but also because Perjeta causes severe diarrhoea in some patients. In the clinical trial, roughly one in 10 patients experienced grade three diarrhoea, which means a person can struggle to control their bowel movements and may need to be treated in a hospital or clinic. 'I hope we'll be thoughtful about how we use Perjeta — without causing unnecessary diarrhoea, and without breaking the bank,' he said."

123. *Bloomberg* likewise noted the costs of the drug combination and that the trial barely showed a statistically significant difference in disease free survival between the two groups: "Roche Holding AG's new breast cancer combination therapy barely outperformed a current gold-standard drug for the disease -- the company's own decades-old Herceptin -- in its latest study…. Adding Roche's new medicine Perjeta to Herceptin -- which could double the current monthly cost of $6,100 -- resulted in about 1 percentage point of improvement in the proportion of women who lived at least three years without tumors returning. For patients with less severe cancer, where tumors hadn't spread to the lymph nodes, Perjeta didn't help at all."

124. Additionally, Roche's bad news was good news for its rival Puma Biotech, (whose stock had fallen when Defendants misleadingly touted the positive results of the APHINITY study in the March 2 press release): "[s]hares of rival Puma Biotechnology Inc. jumped 11 percent to $90.70. The underwhelming Roche data could benefit Puma, which also has an experimental drug used in addition to Herceptin."

125. The harsh reaction by oncologists- the ultimate decision-makers as to whether to prescribe Perjeta in an adjuvant setting- confirms that for all practical purposes, the study's results were anything but positive.

126. In an article by Dr. Kathy D. Miller published in the *New England Journal of Medicine*, entitled "Questioning Our APHINITY for More," Dr. Miller explained: "A determination of clinical significance is necessarily more nuanced than the hard numbers that determine statistical significance." In other words, while the APHINITY study (barely) showed a statistically significant difference between the two groups of patients, the results were not clinically meaningful. Dr. Miller highlighted the toxic effects associated with Perjeta, something Defendants misleadingly omitted from their March 2 press release announcing the study's top-line results: "***The short-term and long-term toxic effects associated with the incorporation of pertuzumab [Perjeta] into treatment are not inconsequential***. Increases in diarrhea and rash during therapy were expected, but although

troublesome, they rarely led to treatment discontinuation. However ***the potential increase in cardiac toxic effects, with their attendant long-term consequences requires greater attention***." Dr. Miller unequivocally concluded: "***The toxic effects (and cost) are too great for too many to benefit too few.***" (Emphasis added).

127. Oncologists in attendance at the ASCO conference, where Roche presented the results from the APHINITY study, confirmed that clinicians would not prescribe Perjeta in an adjuvant setting based on the results of the APHINITY study. Dr. William Sikov, from the Program in Women's Oncology at the Women and Infants Hospital of Rhode Island and Associate Professor of Medicine at the Alpert Medical School of Brown University, commented on the marginal benefit compared to the high cost of adding Perjeta: "To treat 100 patients with pertuzumab [Perjeta] on top of standard therapy would cost $10 million dollars. With a 2% improvement, this means paying $5 million for each patient who does not recur, and ***the study will never demonstrate a survival advantage***. I can think of a lot better things to do with $5 million [of health-care dollars]," Dr. Sikov commented. Dr. Sikov continued: "The problem is that we don't live in utopia, where treatments have no financial or toxicity costs… ***Until we have more robust clinical or biologic indicators for which patients are going to benefit from these treatments, it would be irresponsible to add these to our standard regimens*** for a

wide range of patients who are at slightly higher risk. These are patients who do very well with standard therapy." (Emphasis added).

128. Renowned Oncologist Dr. Steven Vogl, who is affiliated with Montefiore Medical Center in New York City and White Plains Hospital, published a detailed article in the *ASCO Post* stating that the data from the APHINITY study did not show a statistically significant benefit: "The proper interpretation of these data is that distant events may be delayed or prevented by adding pertuzumab [Perjeta], ***but so far this benefit is not statistically significant, nor has a significant improvement in distant disease-free survival been reported*** (there will be some deaths without prior distant disease, usually not due to the breast cancer itself)." Dr. Vogl concluded: "***So far, pertuzumab [Perjeta] has not improved overall survival at all, nor has it reduced distant relapses to a statistically significant extent***…Except in situations of extraordinary risk (HER2-porisive cancer that is locally advanced or with massive matted axillary nodes), ***the argument for recommending adjuvant pertuzumab are weak, and those for investing the huge resources demanded to pay for it are even weaker***…" (Emphasis added).

129. Despite the consensus by Oncologists that the study was a disappointment, Jose Baselga spoke at ASCO telling analysts that the critiques were "weird" and "strange."

130. Analysts responded harshly to news of the APHINITY study results, lowering their forecasts and price targets for Roche securities. Analyst Liberium's comment confirms the false and misleading nature of Defendants' March 2 press release, in which he said: "[t]his was not the result that we or consensus were looking for, particularly given the positive update in March and the powering of the trial".

131. Credit Suisse removed Roche from its "Focus List" stating "[w]e remove Roche from the Credit Suisse Focus List following disappointing headline APHINITY data on the efficacy of the Perjeta/Herecptin combination in HER2+ breast cancer…We no longer see the risk/reward profile as acceptable for a Focus List stock"

132. The day after Roche revealed the true results from the APHINITY study HSBC cut its forecast and price target, commenting on the implications of the study results: "APHINITY data a disappointment...The primary efficacy end-point, the difference in invasive disease-free survival just hit statistical significance [ ]… The weak APHINITY data have bigger implications than Perjeta not being included with Herceptin in the standard of care on HER2+ve breast cancer. If APHINITY had been more positive, it would at least have given Roche the chance to bundle Herceptin and Perjeta in the adjuvant setting and set a competitive price in light if imminent biosimilar competition. ***That opportunity is now gone, leaving***

the HER2 breast cancer franchise more exposed to biosimilar competition." (Emphasis added).

133. The same day Kepler Cheveux likewise lowered its price target for Roche, noting not only the marginal results from the study but the costs and safety risks of adding Perjeta to adjuvant treatment:

> The disappointing APHINITY results at ASCO yesterday mean Perjeta in adjuvant will likely only be used in a minority of high-risk patients…The absolute incremental benefit provided by Perjeta was to prevent cancer recurring in just 0.9% of women in the study. This is lower than the markets, and we, had imagined. ***As we highlighted before, this would imply a treatment cost of up to USD7m per cancer recurrence prevented across the whole study population (which was already enriched with high-risk patients with node-positive cancers)…To add to low efficacy, another concern is that the safety of adding Perjeta is not as benign as we had thought***. Cardiac issues are a meaningful concern: heart failure of cardiac death in 0.7% of patients on Perjeta (vs. 0.3% on the control arm, borderline significant) is a disincentive for lower-risk patients to get Perjeta. ***Additionally, 10% of patients saw severe (grade >=3 diarrhoea (versus 4%): another reason not to use Perjeta***."
>
> ***
>
> "***universal usage of Perjeta across the adjuvant HER2 population is not going to happen…We think pressure from biosimilars will start to dominate more of market thinking on Roche***. Roche has been clear that future margin expansion depends on the pipeline really delivering, but APHINITY has not."
>
> (Emphasis added).

134. Indeed, the given the true results of the APHINITY study, sales of Perjeta in the adjuvant setting did not increase, and revenues from a Herceptin/Perjeta combination did not offset lost revenues from Herceptin due to biosimilar competition in Europe, where a Herceptin biosimilar was already on the market. In reporting on Q3 2017 a SeekingAlpha report stated: "HER2 franchise sales (Herceptin, Perjeta and Kadycycla) were CHF 1.4% lower than consensus, driven by a weak performance of Herceptin in Europe and Perjeta. ***It's worth noting that there hasn't been any acceleration of the growth trajectory for Perjeta after the disappointing results from the Phase III trial APHINITY, assessing the benefits of adding Perjeta to Herceptin in adjuvant HER2-positive breast cancer."*** (emphasis added).

135. Nearly all of the other conference participants concluded that the Study results were disappointing and were not clinically meaningful. It was not until after the close of the Class Period that Dr. Baselga's positive statements touting the Study results at the June 2017 ASCO conference made sense. He had been bought and paid for by Roche.

136. On September 8, 2018 the New York Times, in collaboration with the nonprofit journalism organization *ProPublica*, published an article entitled "Top Cancer Researcher Fails to Disclose Corporate Financial Ties in Major Research Journals." The article revealed that Dr. Jose Baselga, the Chief Medical Officer at

Memorial Sloan Kettering Cancer Center in New York failed to disclose millions of dollars in payments from drug and health care companies, Roche most prominent among them. The article went on to state:

> At a conference this year and before analysts in 2017, he put a positive spin on the results of two Roche-sponsored clinical trials that many others considered disappointments, without disclosing his relationship to the company. Since 2014, he has received more than $3 million from Roche in consulting fees and for a stake in a company it acquired
>
> ***
>
> Among the most prominent relationships that Dr. Baselga has often failed to disclose is with the Swiss pharmaceutical giant Roche and its United States subsidiary Genentech. In June 2017, at the annual meeting of the American Society of Clinical Oncology in Chicago, Dr. Baselga spoke at a Roche-sponsored investor event about study results that the company had been counting on to persuade oncologists to move patients from Herceptin- which was facing competition from cheaper alternatives—to a combination treatment involving Herceptin and a newer, more expensive drug, Perjeta. The results were so underwhelming that Roche's stock fell 5 percent on the news. One analyst described the results as a "lead balloon," and an editorial in the New England Journal called it a 'disappointment.' Dr. Baselga, however, told analysts that the critiques were 'weird' and 'strange.'

137. The article noted that Dr. Baselga improperly concealed that his ties to Roche went beyond serving as a trial investigator in the APHINITY study. The article also revealed that in 2014 Roche acquired Seragon, a cancer research company that Baselga owned a stake in, for $725 million. Baselga received more than $3 million in 2014 and 2015 for his stake of the company. With respect to his failure to follow financial disclosure rules set by the American Association for

Cancer Research he stated "I acknowledge that there have been inconsistencies, but that's what it is." ASCO said that it would conduct an internal review of Baselga's disclosures and refer the findings to a panel.

138. Several days after the New York Times article broke Baselga resigned as chief medical officer of Memorial Sloan Kettering, where he had been paid a salary of $1.5 million in 2016.

139. The Chairman of the Board of Memorial Sloan Kettering privately told the hospital's staff that Baselga had "crossed the line" and "gone off the reservation" in his outside dealing with pharmaceutical companies.

140. The American Association for Cancer Research also forced Baselga resign from his post as editor-in-chief of its medical journal *Cancer Discovery* because he "did not adhere to the high standards" of conflict of interest disclosures that the group expects.

141. Baselga was forced to correct his disclosures with ASCO. ASCO stated that Baselga's participation in future meetings would be contingent upon it first reviewing his presentation slides and that his sessions would be monitored for evidence of bias. ASCO also said if Baselga again failed to disclose his financial relationship he would be barred from participating in ASCO sponsored meetings for two years.

142. Underscoring the misleading nature of discussing the APHINITY Study while failing disclose Roche's financial ties to Baselga, on October 18, 2018 the New England Journal of Medicine published a correction, correcting the inaccuracies in the publication of the APHINITY Study. The Journal's correction stated that the article on the APHINITY Study should have included a statement disclosing that Dr. Baselga received "personal and other fees" from Roche/Genentech (among others). The Editor's note states: "Dr. Baselga failed to disclose his multiple, substantial financial associations, which are now apparent in the updated disclosure forms. When we learned of this breach of trust, we conveyed our concerns to Dr. Baselga's institution, Memorial Sloan Kettering Cancer Center."

143. In a New York Times article, Marcia Angel, a faculty member at Harvard Medical School and former Editor in Chief of the New England Journal of Medical, commented on the dangers of nondisclosure of conflicts of interest and how payments by pharmaceutical companies to clinical researches infects the accuracy of clinical study results:

> There's good evidence that drug company involvement biases research in ways that are not always obvious, often by suppressing negative results. A review of 74 clinical trials of antidepressants, for example, found that 37 of 38 positive studies — that is, studies that showed that a drug was effective — were published. But 33 of 36 negative studies were either not published or published in a form that conveyed a positive outcome. Bias can also be introduced through the design of a clinical trial. For example, the sponsor's drug may be

> compared with another drug administered at a dose so low that the sponsor's drug looks more powerful. Or it can be compared with a placebo, when the relevant question is how it compares with an existing drug. In short, it's often possible to make clinical trials come out the way you and your sponsors want.

144. Dr. Angel provided an example from her personal experience as editor at the New England Journal of Medicine illustrating how financial ties between pharmaceutical companies and clinical researchers can lead to publication of misleading and inaccurate study results:

> I was an editor of The New England Journal of Medicine for over two decades, and was there in 1984 when we became the first major medical journal to institute a policy that required authors of research articles to disclose all financial ties to companies that could be affected by their research. We had become aware that academic researchers were receiving large payments from drug companies and that it was distorting their work. For example, I once phoned the senior author of a paper submitted to us to ask why he had neglected to mention the side effects of a potent new drug he was testing. Without any apparent embarrassment, he said that the sponsor wouldn't let him. We didn't publish the paper, but another journal did. 145.

Materially False and Misleading Statements

146. The Class Period begins on March 2, 2017. By that time Defendants had the complete results from the APHINITY study, including all of the study data and a complete statistical analysis of the study data.

147. On March 2, 2017 Roche issued a press release entitled "Phase III APHINITY study shows Roche's Perjeta® regimen helped people with an

aggressive type of early breast cancer live longer without their disease returning compared to Herceptin® and chemotherapy." The press release stated in pertinent part:

> **Phase III APHINITY study shows Roche's Perjeta® regimen helped people with an aggressive type of early breast cancer live longer without their disease returning compared to Herceptin® and chemotherapy**
>
> - ***Perjeta plus Herceptin and chemotherapy showed a statistically significant improvement in invasive disease-free survival (iDFS) for people with HER2-positive early breast cancer (eBC) compared to Herceptin and chemotherapy alone***
> - Data will be discussed with health authorities, including the US Food and Drug Administration (FDA) and European Medicines Agency (EMA)
>
> Roche (SIX: RO, ROG; OTCQX: RHHBY), the Breast International Group (BIG), Breast European Adjuvant Study Team (BrEAST) and Frontier Science Foundation (FS) today announced positive results from the phase III APHINITY study. The study met its primary endpoint ***and showed that adjuvant (after surgery) treatment with the combination of Perjeta® (pertuzumab), Herceptin® (trastuzumab) and chemotherapy (the Perjeta-based regimen) achieved a statistically significant reduction in the risk of recurrence of invasive disease or death (invasive disease-free survival; iDFS) in people with HER2-positive early breast cancer (eBC)*** compared to Herceptin and chemotherapy alone. The safety profile of the Perjeta-based regimen was consistent with that seen in previous studies[1], and ***no new safety signals were identified***. Full results from the APHINITY trial will be presented at an upcoming medical meeting in 2017.
>
> (Emphasis added).

148. The March 2 press release also described Roche and its study partners. In describing the Breast International Group (BIG) the press release stated that "BIG is a not-for-profit organization for academic breast cancer research groups from around the world, based in Brussels Belgium. Global collaboration is crucial to make significant advances in breast cancer research…Therefore, BIG facilitates breast cancer research at an international level, by stimulating cooperation between its members and other academic networks, and collaborating with, ***but working independently from, the pharmaceutical industry.*** (Emphasis added). This demonstrates that Roche fraudulently pointed to BIG's excellent reputation for reliable and independent clinical research to persuade investors that the Study results were strong, when in reality they were not.

149. The March 2 press release was materially false and misleading for the following reasons: (i) while the study technically met its endpoint it did not also show that adjuvant treatment with Perjeta, Herceptin and chemotherapy achieved a statistically significant reduction in the risk of recurrence of invasive disease-free survival in people with HER2-positive early breast cancer compared to Herceptin and chemotherapy alone because: a) the results barely met the test for statistical significance, b) the entire purported improvement in the rate of cancer recurrence was attributable to only one subgroup within the trial, c) the improvement in patients given Perjeta was marginal overall and would not be considered clinically

significant by the medical community and prescribers; and (ii) new safety signals (*i.e.* dangers) were in fact identified because: a) the group of patients treated with Perjeta experienced significantly higher rates of diarrhea (1 in 10 patients with treated with Perjeta experienced severe diarrhea), which in cancer patients is dangerous and can lead to hospitalization, b) the group of patients treated with Perjeta experienced substantially higher incidents of primary cardiac arrest and heart failure, (c) the rate of patient discontinuation due to adverse events was 1.1 percentage points higher in the group of patients treated with Perjeta compared to those treated with placebo. At the very least, Defendants were required to disclose that the overall difference in study patients treated with Perjeta compared to those treated with placebo was marginal, that the improvement inured only one subgroup, and that patients treated with Perjeta experienced higher rates of diarrhea and other adverse events in order to make the press release not materially false and misleading. Additionally, Defendants were aware that the above statements were materially misleading because: (i) they were aware of the high bar for success of the APHINITY study; (ii) they were aware of analysts' and the markets' expectations and standards for the APHINITY study to be deemed a success, and were aware that the study results did not in fact meet those standards; and (iii) they were aware that once the true results of the study were made public

the reaction on the part of clinicians, analysts and investors would be overwhelmingly negative.

150. The March 2 press release was materially false and misleading for the additional reason that it omitted to disclose that the author of the APHINITY study and clinical researcher on the Study, Jose Baselga, had a financial relationship with Roche such that Roche had made payments to him of over three million dollars. Roche's undisclosed conflict of interest with Baselga and Baselga's bias tainted the reliability of statements concerning the APHINITY Study and the Study itself. Roche was duty bound to disclose Baselga's authorship and financial relationship with Roche in order to make the statements it did make concerning the APHINITY Study not misleading. Indeed, the New England Journal of Medicine's publication of a *correction* to the Study based on Baselga's failure to disclose his conflict of interest with Roche demonstrates that Defendants' were duty bound to disclose this blatant conflict to prevent statements they did make about the APHINITY Study from misleading investors.

151. The March 2 press release was materially false and misleading for the additional reason that it affirmatively represented Roche's study partner, BIG, as "working independently from the pharmaceutical industry" but failed to disclose that Roche had made payments of over three million dollars to Jose Baselga, an executive member of BIG and collaborator and author of the APHINITY study.

Once Defendants touted the Study results by relying on the purported independence of BIG, Defendants were duty-bound to disclose this blatant conflict of interest to prevent their positive statements about the Study results from misleading investors.

152. Defendant O'Day discussed the results of the APHINITY study on Roche's April 27, 2017 first quarter investor conference call (the "1Q 2017 Investor Call"). O'Day stated: "And with the APHINITY trial, you see how that chart nicely filled out, essentially with ***one medicine in combination has been able to improve the standard of care systematically across metastatic, neoadjuvant and now adjuvant.*** APHINITY met its primary endpoint of reducing the risk of recurrence of invasive disease or death compared to Herceptin and chemo alone**.** ***And this is really I think terrific news for patients because we're really talking about a curative setting here with early breast cancer. We are really looking forward to presenting the results to you at ACSO….Based on the APHINITY results, I mean, we can absolutely be confident to continue to grow this franchise through the introduction of biosimilars***, which will start in Europe in the second half of this year." (Emphasis added). Accordingly, O'Day assured that market that the results of the APHINITY study outcome was "terrific news" and that the improvement that Perjeta brought to breast cancer patients when used in an

adjuvant setting would provide Roche with the market opportunity necessary to thwart erosion in the Company's sales growth from biosimilar competition.

153. O'Day additionally reassured the market that the use of Perjeta in an adjuvant setting would thwart biosimilar competition because Perjeta now showed a "significant increase in the standard of care" in "all the indications":

> ..[A]s we look forward at the HER2 franchise, we consider that—we're still going to compete on Herceptin. I mean, that doesn't go away. ***We've now got Perjeta showing significant increase in the standard of care and all the indications*** at a 2x price. It doesn't take a lot of faith to suggest and to be convinced that we can grow this franchise through the biosimilar erosion, particularly because, remember, the biosimilar erosion curve is not happening in one year, but it's happening over multiple years…it enters first in Europe and enters in the U.S. And of course, how it enters will allow us to make sure that we can have sufficient time to get the update on Perjeta around the globe. (Emphasis added).

154. The above statements Defendant O'Day made on the 1Q 2017 Investor Conference Call were materially false and misleading because the results of the APHINITY trial did not "improve the standard of care" in the adjuvant setting due to the facts that: a) the National Cancer Institute defines "standard of care" as "treatment that experts agree is appropriate, accepted and widely used"; b) given this definition the APHINTY trial did not "improve the standard of care" because the study results only supported using the treatment in one subgroup of patients c) the results barely met the test for statistical significance; d) the entire purported improvement in the rate of cancer recurrence was attributable to only

one small subgroup within the trial and would not protect Herceptin sales from biosimilar competition; e) the improvement in patients given Perjeta was marginal overall and would not be considered clinically significant by the medical community and prescribers; and f) the group of patients treated with Perjeta experienced significantly higher rates of diarrhea (1 in 10 patients with treated with Perjeta experienced severe diarrhea), which in cancer patients can lead to hospitalization. Further, the APHINITY study results did not support "contin[uing] to grow this franchise [the HER2 franchise] through biosimilar competition" because due to the dismal results of the APHINITY study doctors would not be widely prescribing Perjeta in an adjuvant setting, and revenues from the Perjeta/Herceptin combination would not offset revenues lost from biosimilar competition or help Roche continue to grow the HER2 franchise. For the same reasons, the study outcome was not "terrific news." Additionally, Defendant O'Day's statement that one medicine in combination has been able to improve the standard of care *systematically* across metastatic, neoadjuvant and now adjuvant was knowingly highly false and misleading because it implied that the study results supported making Herceptin plus Perjeta the new standard of care which it did not. O'Day was in possession of the study data which demonstrated that the improvement applied to one small subgroup in the study, not to the entire study

population, and therefore there would be no "systematic" change in treatment of HER2-positive early breast cancer in the adjuvant setting.

155. Even if O'Day's statement that the APHINITY trial would "improve the standard of care systematically" is considered an opinion statement, O'Day lacked a reasonable basis for making the statement because he was aware of facts (i.e. the study results) demonstrating that the study results did not show that the addition of Perjeta improved the standard of care "systematically" because: (1) the marginal 0.9% benefit from adding Perjeta to Herceptin meant that it did not improve the standard of care "systematically" and (2) the benefit which inured to one study subgroup meant that the improvement was not "systematic" but was instead isolated to that one subgroup.

156. Further, Defendant O'Day's statement that we are "looking forward to presenting the results to you at ASCO" implies that the results were positive and would be well-received by clinicians and investors. In reality, Defendant O'Day was well aware that the study results did not meet clinicians,' analysts' and investors' expectations for success and that when the results were presented at ASCO the response would be overwhelmingly negative.

157. On the 1Q 2017 Investor Conference Call Defendant O'Day fielded questions from analysts about the APHINITY study:

> Q: I know you don't want to say much on APHINITY ahead of ASCO, ***but hoping I can get your level of confidence from the***

> ***robustness of the results in another way because, as you know, there's lots of debate about the magnitude and the benefit and that sort of thing***. So consensus currently models peak Perjeta sales of around CHF[8] 4.5 billion. As a reference of course, Herceptin currently falls around CHF 7 billion a year. I'm hoping you can give us some indication whether you think those out-year numbers seem reachable or could they be too high or low.

158. O'Day responded, assuring investors that while the full results could not be divulged until the ACSO conference, the results were clinically meaningful and demonstrated a clinically meaningful reduction in the recurrence of disease in patients treated with the Perjeta/Herceptin combination:

> So yeah, you're right. I mean, obviously for the sake of the cooperative group, for our sake, for the sake of ASCO, we have to really wait until ASCO to get into the details. But suffice it to say that we think this is the data we filed, where we think ***the data shows a reduction in risk recurrence in invasive breast cancer and we think they're clinically meaningful.*** I think that's about as much as I'm going to open the envelope on today until you see the additional data. (Emphasis added).

159. Defendant O'Day's above-statement that the "data shows a reduction in risk recurrence in invasive breast cancer" that is "clinically meaningful" was materially false and misleading because: a) the data barely showed a statistically significant reduction in risk recurrence in invasive breast cancer, let alone a reduction in risk that was clinically significant; b) the overall difference in study

[8] "CHF" indicates Swiss Francs. 1 CHF equals approximately $1.07, presently. During the Class Period on average, 1 CHF was equal to approximately $1.03.

patients treated with Perjeta compared to those treated with placebo was only marginal; c) the data showed that only one subgroup within the study showed *any* improvement in the rate of cancer recurrence; d) the improvement in patients given Perjeta was marginal overall and would not be considered clinically significant by the medical community and prescribers; and e) the study patients treated with Perjeta experienced higher rates of diarrhea and other adverse events.

Additional Motive Allegations

160. Defendants issued the March 2 press release despite knowing that the data from the APHINITY study did not show a clinically significant or a clinically meaningful benefit from adding Perjeta in an adjuvant setting and that the APHINITY study results meant that a Perjeta/Herceptin combination would not become the new standard of care and would not be widely prescribed by clinicians. By announcing positive results for the APHINITY study, Roche made investors believe that Perjeta in an adjuvant setting would be widely used and Roche would protect sales of Herceptin against biosimilars and therefore earn substantial profits from the use of Perjeta in an adjuvant setting and that the value of its stock would rise accordingly. Defendants therefore artificially inflated the price of the Company's securities so that they could earn a quick profit by selling over $13.1 million of Roche shares before having to announce the true results from the APHINITY study at the ASCO conference.

161. Roche's undisclosed payments of millions of dollars to Dr. Jose Baselga, a study collaborator and author who touted the Perjeta/Herceptin combination despite the dismal study results additionally supports an inference of scienter.

APPLICABILITY OF PRESUMPTION OF RELIANCE:

Fraud-on-the-Market Doctrine

1. Plaintiffs are entitled to rely, and will rely, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

b. the omissions and misrepresentations were material;

c. Roche securities are traded in efficient markets;

d. the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of Roche's securities; and

e. Plaintiff and members of the Class purchased, acquired and/or sold Roche securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

162. At all relevant times, the market for Roche ADS was an efficient market for the following reasons, among others:

- Roche's ADS met the requirements for listing, and were listed and actively traded on the OTCQX, an highly efficient and automated market;

- Roche shares were also listed on the SIX Swiss stock exchange in Europe providing very deep trading markets;

- During the Class Period, the average weekly trading volume for Roche ADS on the OTCQX Market was 5,517,977 shares, which represents approximately 1% of ADS available for sale during the Class Period permitting a strong presumption of reliance;

- At least 12 stock market analysts followed Roche and wrote a total of at least 50 reports on Roche during the Class Period. Analysts covering Roche included Morgan Stanley, JP Morgan, Morningstar, Société Générale, Deutsche Bank, UBS, Credit Suisse, Jeffries and Liberium;

- Roche regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

- More than 25 member firms were active market-makers in Roche ADS at all times during the Class Period;

- During the Class Period Roche was eligible for S-3 registration (or F-3 in Roche's case as a foreign private issuer), with a tradeable float in excess of $75 million;

- Roche's market capitalization exceeded $2 billion on all days during the Class Period;

- Unexpected material news about Roche was rapidly reflected and incorporated into the Company's ADS price during the Class Period. For example, when Defendants issued the misrepresentation about the APHINITY study on March 2, 2017, Roche's share price spiked up a

> material amount, and when Roche disclosed the truth about the APHINITY study results on June 5, 2017, its share price immediately declined a material amount.

163. As a result of the foregoing, the market for Roche promptly digested current information regarding Roche from all publicly available sources and reflected such information in Roche's ADS price. Under these circumstances, all purchasers of Roche ADS during the Class Period suffered similar injury through their purchase of Roche ADS at artificially inflated prices, and a presumption of reliance applies.

Affiliated Ute

164. Neither Plaintiffs nor the Class need prove reliance – either individually or as a class because under the circumstances of this case, positive proof of reliance is not a prerequisite to recovery, pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security.

PLAINTIFFS' CLASS ACTION ALLEGATIONS

165. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all persons who purchased Roche ADS during the Class Period and who were damaged

thereby. Excluded from the Class are Defendants, the officers and directors of the Company at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

166. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Roche's ADS were actively traded on the OTCQX Marketplace. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are at least hundreds of members in the proposed Class. Members of the Class may be identified from records maintained by Roche or its transfer agent and may be notified of the pendency of this action by mail, using a form of notice customarily used in securities class actions.

167. Plaintiffs' claims are typical of the claims of the members of the Class, as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

168. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

169. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Roche;

(c) whether the Individual Defendants caused Roche to issue false and misleading statements during the Class Period;

(d) to what extent the members of the Class have sustained damages and the proper measure of damages.

170. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to redress individually the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Against All Defendants

171. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

172. This Count is asserted against the Company and the Individual Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

173. During the Class Period, the Company and the Individual Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

174. The Company and the Individual Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they: employed devices, schemes and artifices to defraud; made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others

similarly situated in connection with their purchases of the Company's securities during the Class Period.

175. The Company and the Individual Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These defendants by virtue of their receipt of information reflecting the true facts of the Company, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning the Company, participated in the fraudulent scheme alleged herein.

176. Individual Defendants, who are the senior officers and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiffs and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements

made by them or other personnel of the Company to members of the investing public, including Plaintiffs and the Class.

177. As a result of the foregoing, the market price of the Company's ADS were artificially inflated during the Class Period. In ignorance of the falsity of the Company's and the Individual Defendants' statements, Plaintiffs and the other members of the Class relied on the statements described above and/or the integrity of the market price of the Company's securities during the Class Period in purchasing the Company's securities at prices that were artificially inflated as a result of the Company's and the Individual Defendants' false and misleading statements.

178. Had Plaintiffs and the other members of the Class been aware that the market price of the Company's securities had been artificially and falsely inflated by the Company's and the Individual Defendants' misleading statements and by the material adverse information which the Company and the Individual Defendants did not disclose, they would not have purchased the Company's securities at the artificially inflated prices that they did, or at all.

179. As a result of the wrongful conduct alleged herein, Plaintiffs and other members of the Class have suffered damages in an amount to be established at trial.

180. By reason of the foregoing, the Company and the Individual Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to Plaintiffs and the other members of the Class for substantial damages which they suffered in connection with their purchases of the Company's securities during the Class Period.

COUNT II

Violation of Section 20(a) of the Exchange Act Against The Individual Defendants

181. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

182. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information regarding the Company's business practices.

183. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to the Company's financial condition and results of operations, and to correct promptly any public statements issued by the Company which had become materially false or misleading.

184. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which the Company disseminated in the marketplace during the Class Period. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause the Company to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of the Company's securities.

185. Each of the Individual Defendants, therefore, acted as a controlling person of the Company. By reason of their senior management positions and/or being directors of the Company, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, the Company to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of the Company and possessed the power to control the specific activities which comprise the primary violations about which Plaintiffs and the other members of the Class complaint.

186. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

COUNT III

Violation of Section §20(A) of the Exchange Act Against the Individual Defendants (Insider Trading)

187. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

188. This claim is brought against Individual Defendants Hippe, Schwan, O'Day and Keller under §20A of the Exchange Act, 15 U.S.C. §78t-1 on behalf of the §20A Subclass. Between March 3, 2017 and May 10, 2017 the Individual Defendants members of Roche's Corporate Executive Committee board sold CHF 12,796,757 (approximately $13,152,849) worth of Roche securities. Lead Plaintiff Kevin Gardeck purchased 5,750 shares of Roche ADS at $32.16 and 4,500 shares of Roche ADS at $32.23 on March 28, 2017 which is within a day of insider sales.

189. As stated herein, the Individual Defendants were aware of and/or recklessly disregarded the true results of the APHINITY study and the Company's true financial condition.

190. The Individual Defendants had access to Roche's material, nonpublic and highly confidential information concerning the data and results from the APHINITY study prior to the issuance of Roche's March 2 press release and the knowledge that the March 2 press release and statements made on Roche's investor calls concerning the APHINITY trial results were materially misstated during the

Class Period. By virtue of the Individual Defendants' receipt thereof, the Individual Defendants were duty bound not to benefit therefrom and either disclose the true facts about the study results or refrain from trading Roche securities, a duty which they violated by selling their shares at inflated prices.

191. The Individual Defendants thereby violated Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5.

192. The measure of damages for trading while in possession of material nonpublic information under Section 20A of the Exchange Act, 15 U.S.C. § 78t-1, is the disgorgement of profits gained and losses avoided by such trading.

193. Plaintiff Gardeck and the Subclass of investors who likewise purchased Roche shares contemporaneously with the Individual Defendants' March 3, 2017 through May 10, 2017 insider sales are entitled to disgorgement of the amounts by which the Individual Defendants profited from such trades.

194. By virtue of the foregoing, the Individual Defendants are liable for violations of Section 20A of the Exchange Act, 15 U.S.C. § 78t-1.

195. This action was filed within two years of discovery of the fraud and within five years of Plaintiff's purchases of securities giving rise to the cause of action.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiffs and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiffs and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiffs hereby demand a trial by jury.

Dated: April 24, 2019

Respectfully submitted,

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